

FORM 10-QSB
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

**Quarterly Report Pursuant to Section 13 or 15(d) of the
Securities Exchange Act of 1934**

For the Quarterly Period Ended September 30, 2007

Commission File Number 0-26694

SPECIALIZED HEALTH PRODUCTS INTERNATIONAL, INC.
(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of
incorporation or organization)

93-0945003
(IRS Employer Identification No.)

585 West 500 South, Bountiful, Utah 84010
(Address of principal executive offices, including zip code)

(801) 298-3360
(Registrant's telephone number, including area code)

Check whether the issuer (1) filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☒

State the number of shares outstanding of each of the issuer's classes of common equity, as of the latest practicable date.

<u>Class</u>	<u>Outstanding as of November 7, 2007</u>
Common Stock, \$.02 par value	68,333,633 shares

Transitional Small Business Disclosures Format (check one): Yes ☐ No ☒

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PART I — FINANCIAL INFORMATION

Item 1. Financial Statements

SPECIALIZED HEALTH PRODUCTS INTERNATIONAL, INC. AND SUBSIDIARIES CONDENSED CONSOLIDATED BALANCE SHEETS

	September 30, 2007 (unaudited)	December 31, 2006
Assets		
Current Assets:		
Cash and cash equivalents	\$ 4,097,117	\$ 2,281,680
Available-for-sale securities	4,175,000	4,275,375
Accounts receivable, net	2,573,901	2,680,865
Inventory	2,058,756	2,028,020
Prepaid expenses and other	379,430	368,942
Total Current Assets	<u>13,284,204</u>	<u>11,634,882</u>
Property and Equipment, net of accumulated depreciation of \$1,492,127 and \$1,234,411 at September 30, 2007 and December 31, 2006, respectively	1,256,163	1,282,119
Intangible assets, net	2,806,300	2,805,032
Goodwill	586,161	870,980
Other assets	33,655	30,987
	<u>\$ 17,966,483</u>	<u>\$ 16,624,000</u>
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	\$ 1,047,898	\$ 1,699,869
Accrued liabilities	932,457	1,354,003
Accrual for patent litigation expenses	508,409	911,376
Deferred revenue	191,668	196,668
Total current liabilities	<u>2,680,432</u>	<u>4,161,916</u>
Deferred revenue, net of current portion	29,566	172,067
Total liabilities	<u>2,709,998</u>	<u>4,333,983</u>
Commitments and contingencies (Note 4)	-	-
Stockholders' equity:		
Series A preferred stock, \$.001 par value; 20,000,000 shares authorized, no shares issued and outstanding at September 30, 2007 and December 31, 2006	-	-
Common stock, \$.02 par value; 80,000,000 and 70,000,000 shares authorized, 68,333,633 and 67,305,207 shares issued and outstanding at September 30, 2007 and December 31, 2006, respectively	1,366,673	1,346,104
Additional paid-in capital	51,508,601	50,390,139
Accumulated deficit	(37,618,789)	(39,446,226)
Total stockholders' equity	<u>15,256,485</u>	<u>12,290,017</u>
Total liabilities and stockholders' equity	<u>\$ 17,966,483</u>	<u>\$ 16,624,000</u>

See accompanying notes to condensed consolidated financial statements.

SPECIALIZED HEALTH PRODUCTS INTERNATIONAL, INC. AND SUBSIDIARIES
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(Unaudited)

	Three Months Ended	
	September 30, 2007	September 30, 2006
Revenue:		
Product sales	\$ 3,833,803	\$ 3,019,536
Royalties	1,121,053	923,114
Technology fees and licensing revenues	49,167	49,167
Development fees and related services	65,260	126,212
	<u>5,069,283</u>	<u>4,118,029</u>
Cost of revenue	<u>1,704,460</u>	<u>1,428,230</u>
	<u>3,364,823</u>	<u>2,689,799</u>
Gross profit		
Operating expenses:		
Research and development (2007 and 2006 totals include amortization of stock based compensation of \$133,950 and \$117,264, respectively)	1,059,368	915,923
Sales and marketing (2007 and 2006 totals include amortization of stock based compensation of \$12,646 and \$7,648, respectively)	282,671	428,740
General and administrative (2007 and 2006 totals include amortization of stock based compensation of \$282,678 and \$228,302, respectively)	990,701	800,933
Total operating expenses	<u>2,332,740</u>	<u>2,145,596</u>
Income from operations	<u>1,032,083</u>	<u>544,203</u>
Other income (expense):		
Interest income	67,597	85,445
Other expense	<u>(3,197)</u>	<u>(72,973)</u>
Total other income, net	<u>64,400</u>	<u>12,472</u>
Income tax provision	<u>(26,619)</u>	<u>-</u>
Net income	<u>\$ 1,069,864</u>	<u>\$ 556,675</u>
Basic net income per common share	\$ 0.02	\$ 0.01
Diluted net income per common share	\$ 0.02	\$ 0.01
Basic weighted average number of shares outstanding	62,932,983	62,632,280
Diluted weighted average number of shares outstanding	66,937,405	64,001,613

See accompanying notes to condensed consolidated financial statements.

SPECIALIZED HEALTH PRODUCTS INTERNATIONAL, INC. AND SUBSIDIARIES
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(Unaudited)

	Nine Months Ended	
	September 30, 2007	September 30, 2006
Revenue:		
Product sales	\$ 10,450,499	\$ 6,949,545
Royalties	2,958,559	1,884,731
Technology fees and licensing revenues	147,501	147,501
Development fees and related services	102,593	532,284
	<u>13,659,152</u>	<u>9,514,061</u>
Cost of revenue	<u>4,642,228</u>	<u>3,344,106</u>
	<u>9,016,924</u>	<u>6,169,955</u>
Operating expenses:		
Research and development (2007 and 2006 totals include amortization of stock based compensation of \$364,553 and \$336,973, respectively)	3,292,409	2,797,465
Sales and marketing (2007 and 2006 totals include amortization of stock based compensation of \$6,735 and \$20,824, respectively)	1,177,231	1,064,351
General and administrative (2007 and 2006 totals include amortization of stock based compensation of \$766,143 and \$651,093, respectively)	<u>2,852,182</u>	<u>2,034,015</u>
Total operating expenses	<u>7,321,822</u>	<u>5,895,831</u>
Income from operations	<u>1,695,102</u>	<u>274,124</u>
Other income (expense):		
Interest income	187,594	114,915
Other expense	<u>(3,314)</u>	<u>(144,274)</u>
Total other income (expense), net	<u>184,280</u>	<u>(29,359)</u>
Income tax provision	<u>(51,945)</u>	<u>(3,435)</u>
Net income	<u>\$ 1,827,437</u>	<u>\$ 241,330</u>
Basic net income per common share	\$ 0.03	\$ 0.00
Diluted net income per common share	\$ 0.03	\$ 0.00
Basic weighted average number of shares outstanding	62,763,836	50,568,408
Diluted weighted average number of shares outstanding	66,397,968	51,033,880

See accompanying notes to condensed consolidated financial statements.

SPECIALIZED HEALTH PRODUCTS INTERNATIONAL, INC. AND SUBSIDIARIES
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(Unaudited)

	Nine Months Ended	
	September 30, 2007	September 30, 2006
Cash flows from operating activities:		
Net income	\$ 1,827,437	\$ 241,330
Adjustments to reconcile net income to net cash provided by (used in) operating activities:		
Depreciation and amortization	498,811	268,357
Amortization of stock based compensation	1,137,431	1,008,890
Amortization of deferred finance cost	-	91,745
Changes in operating assets and liabilities:		
Accounts receivable, net	106,964	(4,417)
Inventory	(30,736)	(348,226)
Prepaid expenses and other	(13,156)	(251,174)
Accounts payable	(651,971)	254,798
Accrued liabilities	(136,727)	(519,353)
Accrual for patent litigation expenses	(402,967)	(357,716)
Deferred revenue	(147,501)	(147,501)
Unamortized rent	-	(3,176)
Deferred rent	-	(3,987)
Net cash provided by (used in) operating activities	<u>2,187,585</u>	<u>229,570</u>
Cash flows from investing activities:		
Purchase of intangible assets	(242,169)	(165,849)
Purchase of property and equipment	(231,954)	(401,093)
Proceeds from maturity of marketable securities	100,375	-
Cash received in connection with acquisition, net of cash paid	-	2,953,498
Net cash provided by (used in) investing activities	<u>(373,748)</u>	<u>2,386,556</u>
Cash flows from financing activities:		
Proceeds from draw against convertible note	-	500,000
Payment of convertible note	-	(1,000,000)
Proceeds from exercise of warrants	1,600	-
Net cash provided by (used in) financing activities	<u>1,600</u>	<u>(500,000)</u>
Net increase in cash and cash equivalents	1,815,437	2,116,126
Cash and cash equivalents at beginning of period	2,281,680	707,222
Cash and cash equivalents at end of period	<u>\$ 4,097,117</u>	<u>\$ 2,823,348</u>
Supplemental non-cash flow information		
Fair value of assets acquired, net of cash received	\$ -	\$ 9,289,560
Fair value of liabilities assumed in merger	\$ -	\$ 2,145,800
Capitalized merger costs paid in 2005	\$ -	\$ 442,720
Purchase price adjustment related to reduction in assumed liabilities	\$ 284,819	\$ -

See accompanying notes to condensed consolidated financial statements.

SPECIALIZED HEALTH PRODUCTS INTERNATIONAL, INC. AND SUBSIDIARIES
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
(Unaudited)

(1) Interim Condensed Consolidated Financial Statements

The accompanying condensed consolidated financial statements have been prepared without audit. In the opinion of management, all adjustments (consisting only of normal recurring adjustments) necessary to present fairly the Company's consolidated financial position, results of operations and cash flows as of the dates and for the periods presented herein have been made.

Certain information and footnote disclosures normally included in financial statements prepared in accordance with accounting principles generally accepted in the United States of America have been condensed or omitted pursuant to the Securities and Exchange Commission's rules and regulations. These condensed consolidated financial statements should be read in conjunction with the consolidated financial statements and notes thereto included in the Company's December 31, 2006 Annual Report on Form 10-KSB. The results of operations for the three and nine months ended September 30, 2007 are not necessarily indicative of the operating results that may be expected for the year ending December 31, 2007. The Company's significant accounting policies are set forth in Note 2 to the consolidated financial statements in the December 31, 2006 Annual Report on Form 10-KSB.

Specialized Health Products International, Inc. ("SHPI") completed its merger with The Med-Design Corporation ("Med-Design") on June 2, 2006, following approval by stockholders of both companies. After completion of the merger, Med-Design stockholders received 21,525,788 shares of SHPI's common stock in exchange for their shares of Med-Design common stock, representing approximately 32.48% of the outstanding shares of SHPI. The financial results included in the three and nine month periods ended September 30, 2007 include combined SHPI and Med-Design operations from January 1, 2007 through September 30, 2007. Financial results for the three months ended September 30, 2006 include combined operations. Financial results for the nine months ended September 30, 2006 include combined operations from June 2, 2006 to September 30, 2006.

The Company's working capital requirements for the foreseeable future will vary based upon a number of factors, including the costs to complete development work, the cost of bringing safety medical needle technologies and other products to commercial viability, the timing of the market launches of new products and the level of sales of the Company's current products. As of September 30, 2007, the Company had accounts payable and accrued liabilities totaling \$1,980,355. The Company also had a current portion of accrued patent litigation expense of \$508,409 and current deferred revenue of \$191,668, neither of which will require the use of cash. At September 30, 2007, the Company had cash and cash equivalents of \$4,097,117 and available-for-sale securities of \$4,175,000. On March 6, 2006, the Company obtained a \$1,500,000 revolving line of credit with Silicon Valley Bank, under which borrowings are collateralized by substantially all of the assets of the Company. Available borrowings are based primarily on outstanding accounts receivable. No funds have been drawn against this credit facility. Management believes that existing cash, cash equivalents and available-for-sale securities, along with cash generated from the collection of accounts receivable, the sale of products, development fees and royalties, and available borrowings under the Company's credit line, will be sufficient to meet the Company's cash requirements during the next twelve months.

Principles of Consolidation

The accompanying condensed consolidated financial statements include the accounts of Specialized Health Products International, Inc. and its wholly-owned subsidiaries, Specialized Health Products, Inc., Safety Syringe Corporation, The Med-Design Corporation, MDC Holdings, Inc. and MDC Research Ltd. All significant intercompany accounts and transactions have been eliminated in consolidation.

Stock-Based Compensation

In December 2004, the Financial Accounting Standard Board ("FASB") issued SFAS No. 123R, "*Share-Based Payments*" (SFAS 123R), a revision of SFAS No. 123, "*Accounting for Stock-Based Compensation*" (SFAS 123), which requires companies to measure all employee stock-based compensation awards using a fair value

method and record such expense in their financial statements. The Company adopted this standard effective January 1, 2006 and elected the modified-prospective transition method. Under the modified-prospective transition method, awards that are granted, modified, repurchased or cancelled after the date of adoption should be measured and accounted for in accordance with SFAS 123R. Stock-based awards that are granted prior to the effective date should continue to be accounted for in accordance with SFAS 123, except that stock option expense for unvested options must be recognized in the statement of operations.

Effective May 2006, the Company's Board of Directors reduced the number of shares authorized and reserved for issuance under the 2000 Stock Option Plan, 2001 Stock Option Plan and 2004 Stock Incentive Plan from 13,500,000 shares to 6,028,000 shares to make sufficient shares of common stock available to issue to former stockholders of Med-Design pursuant to the merger. Effective August 2007, the Company's Board of Directors increased the number of shares authorized and reserved for issuance under the 2000 Stock Option Plan, 2001 Stock Option Plan and 2004 Stock Incentive Plan back to the original amount of 13,500,000 approved by the shareholders. The number of remaining shares authorized under these plans at September 30, 2007 is 7,850,703.

Total stock-based compensation cost for the nine months ended September 30, 2007 was \$1,137,431. During the nine months ended September 30, 2007, 46,911 unvested restricted stock awards were forfeited resulting in the reversal of \$29,169 of cumulative compensation cost recorded in prior periods. Additionally, 73,983 unvested restricted stock awards were modified during the nine months ended September 30, 2007, resulting in an incremental value of \$24,112, which will be expensed ratably over the one year vesting period of the modified awards. Total compensation cost related to granted but unvested awards is approximately \$1,109,004 as of September 30, 2007. The compensation cost will be expensed in future periods and is expected to be recognized over the weighted average period of 1.8 years.

(2) Recent Accounting Pronouncements

In June 2006, the Financial Accounting Standards Board issued FASB Interpretation No. 48, "*Accounting for Uncertainty in Income Taxes, an interpretation of FASB Statement No. 109*" (FIN 48). FIN 48 clarifies the accounting for uncertainty in income taxes recognized in a company's financial statements and prescribes a recognition threshold and measurement attribute for financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return. This Interpretation also provides related guidance on derecognition, classification, interest and penalties, accounting in interim periods and disclosure. FIN 48 is effective for the Company beginning January 1, 2007. The Company adopted FIN 48 at the beginning of fiscal year 2007 with no material impact on its financial condition, results of operations or cash flows.

In September 2006, the FASB issued SFAS No. 157, *Fair Value Measurements*, (SFAS 157). SFAS 157 defines fair value, establishes a framework for measuring fair value in generally accepted accounting principles, and expands disclosures about fair value measurements. The provisions of this standard apply to other accounting pronouncements that require or permit fair value measurements. The Company will adopt SFAS 157 on January 1, 2008. The Company anticipates that the adoption of SFAS 157 will not have a material impact on the Company's consolidated financial statements.

In February 2007, the FASB issued SFAS No. 159, "*The Fair Value Option for Financial Assets and Financial Liabilities*" (SFAS 159). This Statement provides companies with an option to report selected financial assets and liabilities at fair value. Generally accepted accounting principles have required different measurement attributes for different assets and liabilities that can create artificial volatility in earnings. The Statement's objective is to reduce both complexity in accounting for financial instruments and the volatility in earnings caused by measuring related assets and liabilities differently. SFAS 159 is effective for the Company beginning January 1, 2008. The Company is currently evaluating the impact of this standard.

The Company has reviewed all other recently issued, but not yet adopted, accounting standards in order to determine their effects, if any, on its consolidated results of operation, financial position or cash flows. Based on that review, the Company believes that none of these pronouncements will have a significant effect on its current or future earnings or operations.

(3) Basic and Diluted Net Income Per Common Share

The Company generated net income during the three and nine months ended September 30, 2007 and September 30, 2006. The basic net income per common share for 2007 and 2006 are based on the weighted average number of common shares outstanding, excluding unvested restricted stock. The diluted net income per common share for 2007 and 2006 is calculated using the treasury method, adding the number of shares of unvested restricted stock less the assumed repurchase of shares based on the average unrecognized compensation cost and adding the number of warrants and options that are in the money, reduced by the number of shares that would be repurchased from the proceeds of the warrant or option exercises.

At September 30, 2007, options and warrants to purchase 2,879,190 shares of common stock at exercise prices ranging from \$0.02 to \$4.79 per share were outstanding. At September 30, 2006, options and warrants to purchase 3,054,846 shares of common stock at exercise prices ranging from \$0.02 to \$11.23 per share were outstanding. At September 30, 2007 and 2006, there were 5,254,639 and 4,672,871 unvested restricted common shares outstanding, respectively.

The following table sets forth the computation of basic and diluted net income per share for the periods indicated:

	Three Months Ended		Nine Months Ended	
	September 30, 2007	September 30, 2006	September 30, 2007	September 30, 2006
Net Income	\$ 1,069,864	\$ 556,675	\$ 1,827,437	\$ 241,330
Basic weighted average shares outstanding	62,932,983	62,632,280	62,763,836	50,568,408
Effect of dilutive securities:				
Stock warrants	38,924	115,432	38,992	115,086
Unvested restricted common shares	3,965,498	1,253,901	3,595,140	350,386
Dilutive weighted average shares outstanding	<u>66,937,405</u>	<u>64,001,613</u>	<u>66,397,968</u>	<u>51,033,880</u>
Net Income per share				
Basic	\$ 0.02	\$ 0.01	\$ 0.03	\$ 0.00
Diluted	\$ 0.02	\$ 0.01	\$ 0.03	\$ 0.00

(4) Commitments and Contingencies

Purchase Order Commitments

Due to the long lead time of critical components for the LiftLoc®, MiniLoc®, and SafeStep® safety infusion set product lines and the SecureLoc™ Safety Introducer Needle, as of September 30, 2007 the Company had issued \$1,974,293 in long-term purchase orders relating to these products.

Legal Proceedings

In November 1999, the Company entered into a Development and License Agreement (the “Kendall Agreement”) with Kendall, a division of Tyco Healthcare Group LP, relating to the production of a line of safety medical needle products, including six syringe products and five other safety needle products, among which are the Monoject Magellan™ safety products. The Kendall Agreement provides for the Company to receive development fees and ongoing royalties. In the agreement with Kendall the Company agreed to indemnify Kendall for all costs associated with any claims, liabilities, suits or judgments arising out of Kendall’s use of the patent rights and technical information transferred to them under the Agreement.

In December 2002, Becton Dickinson (“BD”) filed a lawsuit against Tyco Healthcare, a subsidiary of Covidien Ltd., in the United States Court of the District of Delaware, asserting that Tyco Healthcare’s Monoject Magellan™ safety products infringe upon BD’s U.S. Patent No. 5,348,544 (‘544 Patent), titled “Single-Handedly Actuable Safety Shield for Needles.”

On October 26, 2004, a jury found in favor of BD that Tyco Healthcare’s Monoject Magellan™ safety products willfully infringed the ‘544 Patent and awarded damages of \$4.4 million. On November 1, 2004, the court entered the judgment in favor of BD. Tyco Healthcare challenged the jury finding in post-trial motions, which challenge resulted in the granting of a new trial. The date established for the new trial is in November 2007. Tyco Healthcare developed the Monoject Magellan™ safety products in association with the Company. The Company is not a party to the patent infringement lawsuit.

Under the Kendall Agreement, Tyco Healthcare has the right to withhold up to fifty percent (50%) of royalties due the Company, as an offset against litigation expenses related to charges of infringement by a third party for the manufacture, use or sale of licensed product. This right continues during the period in which such litigation is pending. If, as a result of a judgment in the litigation or settlement with BD, Tyco Healthcare is required to pay royalty and/or other monies to BD, Tyco Healthcare may thereafter deduct from the amount of royalties due the Company on unit sales of products alleged to infringe, an amount which is the lesser of all royalties and/or other monies paid by Tyco Healthcare to BD, or fifty percent (50%) of all royalty payments otherwise payable to the Company. Based on information obtained during the fourth quarter of 2003 related to costs incurred by Tyco Healthcare, the Company recorded a liability of approximately \$1,300,000 at December 31, 2003, which was the Company’s estimate of the portion of costs associated with BD’s lawsuit against Tyco Healthcare that Tyco Healthcare would withhold against the royalties due SHPI through 2005. During the twelve month contract periods ended September 30, 2004 and 2005, Tyco Healthcare withheld fifty percent of royalty payments due the Company, which amounts totaling \$1,000,000 have been offset against the accrual. Based on information obtained during the fourth quarter of 2005, the Company anticipated the litigation would continue at least through 2007. Accordingly, the Company recorded an additional liability of \$1,095,200 at December 31, 2005, which amount was the Company’s estimate of the portion of costs associated with BD’s suit against Tyco Healthcare that Tyco Healthcare will withhold against the royalties due the Company during 2006 and 2007. As of September 30, 2007, there remained \$508,409 of the accrued liability which represents the Company’s estimate of the portion of costs associated with BD’s suit against Tyco Healthcare that Tyco Healthcare will withhold against future royalties due SHPI. In the event litigation continues beyond 2007, or if Tyco Healthcare ultimately loses the case on appeal, additional liabilities may accrue. If Tyco Healthcare is unsuccessful on appeal, Tyco Healthcare may be prohibited from selling the Monoject Magellan™ safety products in their current form. Additional litigation to enforce patents, to protect proprietary information, or to defend the Company against alleged infringement of the rights of others may occur.

In June 2007, Retractable Technologies, Inc. (“RTI”) filed a lawsuit against Becton, Dickinson and Company (“BD”) in the United States Court for the Eastern District of Texas, alleging that the BD Integra™ syringes infringe patents licensed exclusively to RTI. This patent claim was not covered by the release contained in the July 2004 settlement agreement between BD and RTI to settle the lawsuit previously filed by RTI. RTI also alleges in its lawsuit that BD engaged in false advertising with respect to certain of BD’s safety-engineered products in violation of the Lanham Act; acted to exclude RTI from various product markets and to maintain BD’s market share through, among other things, exclusionary contracts in violation of state and Federal antitrust laws; and engaged in unfair competition. The non-patent claims purport to relate to actions allegedly taken by BD following the date of the July 2004 settlement agreement referenced above. RTI seeks treble damages, attorney’s fees and injunctive relief. The Company is not a party to the patent infringement lawsuit brought by RTI against BD.

The Integra™ syringe is the subject of a license agreement dated March 12, 2000, and subsequently amended, between BD and the Med-Design Corporation (“BD Agreement”). Under the BD Agreement, in the event of (i) a final adjudication enjoining BD from making, using, or selling the Integra™ syringe or holding BD liable for damages based on the Integra™ syringe or (ii) settlement of the lawsuit requiring payment of damages by BD relative to the Integra™ syringe, BD has the right to deduct from future royalties sufficient to reimburse itself for one-half of its damages and legal expenses incurred and paid by BD in the lawsuit, but in no event shall BD’s royalty payments be reduced below a one percent (1%) royalty.

On September 6, 2007, Becton Dickinson and Company (“BD”) and MDC Investment Holdings, Inc. (“MDC”) filed a lawsuit against Retractable Technologies, Inc. (“RTI”) in the United States Court for the Eastern District of Texas, asserting that RTI’s VanishPoint® line of syringes infringe upon MDC’s United States Patent No. 6,179,812 (the “‘812 patent”), entitled “Retractable Needle Medical Devices,” and United States Patent No. 7,090,656 (the “‘656 patent”), entitled “Medical Devices with Retractable Needle.” BD and MDC seek damages, attorney’s fees and injunctive relief.

MDC is a wholly owned subsidiary of Med-Design Corporation. Med-Design Corporation is a wholly-owned subsidiary of Specialized Health Products International, Inc. Under a license agreement between BD and MDC, BD is the exclusive licensee with the right to sue for infringement of the ‘812 patent and the ‘656 patent and to join MDC as a party to such suit, in which event BD holds MDC free, clear and harmless from any and all costs and expenses of such litigation, including attorney’s fees.

(5) Income Taxes

At September 30, 2007 and December 31, 2006, the Company had total net operating losses (“NOLs”) of approximately \$86,700,000 and \$90,500,000, respectively that can be utilized to reduce the Company’s future federal income taxes. The Company also has approximately \$1,600,000 of research and experimentation tax credits. The Company utilized these NOLs and tax credits to offset its income tax liability for the three and nine months ended September 30, 2007. However, tax expense of \$26,619 and \$51,945 has been recorded for the three and nine months ended September 30, 2007 for state and federal income taxes since the Company may be subject to certain taxes that cannot be offset by NOLs.

The Company has evaluated its uncertain tax positions as required by FIN 48 and determined that any required adjustments would not have a material impact on the Company’s balance sheet, income statement, or statement of cash flows.

(6) Merger Agreement

The Company completed its merger with The Med-Design Corporation (“Med-Design”) on June 2, 2006, following approval by stockholders of both companies.

Of the preliminary estimated \$2,145,000 of liabilities accrued by the Company in the merger with Med-Design, \$1,281,184 related to expected costs associated with exiting the Med-Design business. During 2007, it was determined, based on early termination of the Med-Design lease, that the actual cost of exiting the Med-Design business was \$996,365, resulting in a decrease of \$284,819 in assumed liabilities and goodwill related to the transaction.

The following unaudited pro forma financial information presents the consolidated results for the nine months ended September 30, 2006, reported as though the business combination had been completed at the beginning of the period. The three and nine months ended September 30, 2007 and three months ended September 30, 2006 include the combined operations. This pro forma financial information is not intended to be indicative of future results.

	Nine Months Ended September 30, 2006
Revenue	\$ 11,310,629
Net loss	(4,650,306)
Basic and diluted net loss per common share:	\$ (0.08)

(7) Capital Transactions

On March 20, 2007 Galen Partners exercised one of its warrants for 80,000 common shares at the exercise price of \$0.02 per share resulting in cash proceeds of \$1,600 to the Company. During the nine months ended September 30, 2007, 46,911 shares of restricted common stock previously granted to employees were forfeited and warrants for 95,656 shares of common stock assumed in the Med-Design merger expired.

In August 2007, the Board of Directors approved the grant of 995,337 shares of restricted stock to certain employees and non-employee directors, resulting in a non-cash charge of \$746,503, which will be expensed ratably over the three year annual vesting period of the stock grants.

In August 2007, 366,658 shares of restricted stock vested. These shares were granted to certain employees and non-employee directors in August 2006.

During the nine months ended September 30, 2007, the number of authorized Series A preferred stock shares was reduced by 10,000,000 from 30,000,000 to 20,000,000 and the number of authorized common stock shares was increased by 10,000,000 from 70,000,000 to 80,000,000 subsequent to approval from the stockholders at the annual meeting of stockholders on May 30, 2007.

(8) Reclassification

Certain prior year amounts have been reclassified to conform to the current year presentation. The effect of these reclassifications had no impact on net income, total assets, total liabilities, or stockholders' equity.

Item 2. Management's Discussion and Analysis and Plan of Operation

This Management's Discussion and Analysis of Financial Condition and Results of Operations and other parts of this quarterly report on Form 10-QSB contain forward-looking statements that involve risks and uncertainties. Forward-looking statements can also be identified by words such as "intends," "anticipates," "expects," "believes," "plans," "predicts," and similar terms. Forward-looking statements are not guarantees of future performance and our actual results may differ significantly from the results discussed in the forward-looking statements. Factors that might cause such differences include, but are not limited to, those set forth below under "Forward-Looking Statements". The following discussion should be read in conjunction with our unaudited condensed consolidated financial statements and notes thereto included in this Form 10-QSB and our audited consolidated financial statements included in our annual report on Form 10-KSB for the year ended December 31, 2006 filed with the Securities and Exchange Commission and management's discussion and analysis contained therein. All information presented herein is based on the three and nine months ended September 30, 2007 and 2006. We assume no obligation to revise or update any forward-looking statements for any reason, except as required by law.

Overview

We design, develop, manufacture, and market proprietary disposable medical devices for clinician and patient safety. Our innovative safety devices are designed to maximize the efficiency and quality of healthcare, while minimizing the risk of accidental needlesticks, which are a leading occupational cause of the spread of blood-

borne diseases such as human immunodeficiency virus and autoimmunodeficiency syndrome (“HIV/AIDS”) and the hepatitis B and C viruses. We have developed multiple safety needle products based upon a broad intellectual property portfolio that applies to virtually all medical needles used today. We manufacture and market certain products, including three of the leading brands in the safety Huber needle market, under our own label. We license or supply other products on an OEM basis to leading manufacturers and marketers in the global disposable medical products industry, including Tyco Healthcare, a subsidiary of Covidien Ltd., Bard Access Systems, and BD Medical.

We completed our merger with The Med-Design Corporation (“Med-Design”) on June 2, 2006. Med-Design was principally engaged in the design and development of safety medical needle products and technologies. Med-Design has a broad intellectual property portfolio that relates primarily to retractable safety needle technology.

The financial results included in the three and nine month periods ended September 30, 2007 includes combined SHPI and Med-Design operations from January 1, 2007 through September 30, 2007. Financial results for the three months ended September 30, 2006 include combined operations. Financial results for the nine months ended September 30, 2006 include combined operations from June 2, 2006 to September 30, 2006.

During the three and nine months ended September 30, 2007, we had total revenue of \$5,069,283 and \$13,659,152 respectively, compared with total revenue of \$4,118,029 and \$9,514,061 for the comparable periods ended September 30, 2006. This relates to an increase in revenue of \$951,254 or 23% for the three months ended September 30, 2007 and \$4,145,091, or 44%, for the nine months ended September 30, 2007, compared to the same periods ended September 30, 2006. The increase in revenue was primarily driven by increased sales of our manufactured products as they continue to gain acceptance in the marketplace, and, for the nine month period, the addition of new revenue streams acquired in our merger with Med-Design. Total revenue derived from Med-Design revenue streams for the nine months ended September 30, 2007 was \$5,964,124. During the nine months ended September 30, 2006, we realized \$1,723,610 of revenue from Med-Design revenue streams.

Gross profit for the three months and nine months ended September 30, 2007 was \$3,364,823 and \$9,016,924 respectively, representing a gross profit margin of 66% for both periods compared to a 65% gross profit margin realized for the comparable periods ended September 30, 2006.

Net income for the three and nine months ended September 30, 2007 was \$1,069,864 and \$1,827,437, respectively, compared to net income of \$556,675 and \$241,330 for the three and nine months ended September 30, 2006. This represents an improvement of \$513,189 or 92% for the three months ended September 30, 2007 and an improvement of \$1,586,107 or 657% for the nine months ended September 30, 2007. Basic net income per share for the three and nine months ended September 30, 2007 was \$0.02 and \$0.03, respectively, compared to basic net income per share of \$0.01 and \$0.00 for the three and nine months ended September 30, 2006, respectively.

We had \$4,097,117 in cash and cash equivalents as of September 30, 2007, representing an increase of \$1,815,437 from December 31, 2006. We also had \$4,175,000 of available-for-sale securities as of September 30, 2007 compared to \$4,275,375 at December 31, 2006. Total cash and cash equivalents and available-for-sale securities was \$8,272,117 at September 30, 2007 compared to \$6,557,055 at December 31, 2006, representing an increase of \$1,715,062. This increase is driven primarily by net cash of \$2,187,585 provided by operating activities during the nine months ended September 30, 2007, offset by cash of \$474,123 used to purchase intangible assets and property and equipment. Net cash of \$2,187,585 provided by operating activities during the nine months ended September 30, 2007 represents an improvement of \$1,958,015 compared to the \$229,570 provided during the same period in 2006.

Sources of Revenue

Revenue consists of (1) product sales, (2) product royalties, (3) technology fees and licensing revenues, and (4) development fees and related services.

Product sales are derived primarily from sales of our manufactured safety Huber needles, safety introducer needles and bone biopsy needles to customers.

Product royalty income is generated from proprietary products subject to license agreements with larger corporate partners, including Tyco Healthcare, BD Medical, and TAP Pharmaceutical Products Inc. In each case,

these products are manufactured and sold by our licensing partners, and we receive on-going royalty payments on product sales.

Technology fees and licensing revenues consist of amortizing up-front payments related to certain license agreements.

Development fees and related services consist of payments for services rendered and reimbursements from our partners related to product development activities.

Cost of Revenue and Operating Expenses

Cost of revenue consists primarily of the raw material and manufacturing cost incurred to build the products sold, plus the cost of inbound and outbound freight.

Research and development expenses consist primarily of personnel and patent costs related to our proprietary research and development efforts and the design, development and improvement of our manufacturing lines and capabilities, as well as costs incurred in connection with our third-party collaboration efforts. Also included is amortization of stock-based compensation cost recorded for restricted stock awards, the value of which is being amortized over the vesting period of the awards in accordance with SFAS 123R.

Sales and marketing expenses consist primarily of payroll and related expenses for personnel engaged in marketing and selling activities, as well as travel, promotional and advertising expenditures incurred to support the sale of our manufactured products. Also included is amortization of stock-based compensation cost recorded for restricted stock awards, the value of which is being amortized over the vesting period of the awards in accordance with SFAS 123R.

General and administrative expenses consist primarily of wages and benefits for executive, legal, accounting and administrative personnel, insurance, rent and utilities, travel, depreciation and amortization of intangible assets and other general corporate expenses. Also included is amortization of stock-based compensation cost recorded for restricted stock awards, the value of which is being amortized over the vesting period of the awards in accordance with SFAS 123R.

Critical Accounting Policies

The application of certain accounting policies requires certain judgments and estimates made by our management that can affect the presentation of the results of our operations, financial position, cash flows and the related footnote disclosures. We base estimates on historical experience and other assumptions, as discussed below, that we believe are reasonable. If actual amounts are ultimately different from previous estimates, we include revisions in our results of operations for the period in which the actual amounts become known. The accounting policies and estimates with the greatest potential to have a significant impact on our operating results, financial position, cash flows and footnote disclosures are as follows:

Revenue Recognition

Pursuant to Staff Accounting Bulletin (“SAB”) No. 104, “*Revenue Recognition*,” we recognize license revenue when the following criteria have been met: (1) persuasive evidence of an arrangement exists, (2) delivery has occurred or services have been rendered, (3) the price is fixed or determinable and (4) collectibility is reasonably assured. Upfront payments relating to license agreements are recognized ratably over the term of the related agreement.

Product revenues are recognized when persuasive evidence of an arrangement exists, risk of loss and title has transferred to our customers, the fee is fixed or determinable and collection is probable. Rights of return for manufactured product are dependent upon the agreement. No right of return is provided for product manufactured under private label, as such product is custom manufactured to order for those distributors. Product manufactured and distributed under our own label does provide rights of return in the case of shipping errors or product received in damaged condition. In addition, distributors have the right, on a quarterly basis, to request the return of excess or slow moving inventory. An accrual for product returns, calculated using historical data, is made at the end of each

quarter. Actual product returns could differ from management's estimates due to changes in future economic or industry conditions or specific customer's inventory sales.

Long-Lived Assets

We regularly evaluate whether events or circumstances have occurred that indicate the carrying value of our long-lived assets may not be recoverable. When factors indicate the asset may not be recoverable, we compare the related undiscounted future net cash flows to the carrying value of the asset to determine if impairment exists. If the expected future net cash flows are less than the carrying value, an impairment charge is recognized based on the fair value of the asset. The estimates of future cash flows involve considerable management judgment and are based upon assumptions about expected future operating performance. The actual cash flows could differ from management's estimates due to changes in business conditions, operating performance and economic conditions. No such impairments were recorded during the three and nine months ended September 30, 2007 and 2006.

Goodwill

We review goodwill for impairment annually. If the fair value exceeds the carrying value of the asset, it is not considered impaired. If its carrying value exceeds its fair value, an impairment loss is recorded to write goodwill down to fair value. Determining the fair value of the asset involves the use of significant estimates and assumptions. These estimates and assumptions include projected revenue growth rates and operating margins to calculate estimated cash flows. No such impairments were recorded during the three and nine months ended September 30, 2007 and 2006.

Stock-Based Compensation

We adopted SFAS 123R on January 1, 2006. We expense stock-based compensation, including stock options, restricted stock and stock awards, using the fair value method. Total compensation costs related to unvested awards to be recorded in future periods was approximately \$1,109,726 as of September 30, 2007. Calculating the fair value of stock-based compensation and recording the stock-based compensation expense requires the use of estimates and assumptions which could differ from actual results.

Recent Accounting Pronouncements

In June 2006, the Financial Accounting Standards Board ("FASB") issued FASB Interpretation No. 48, *"Accounting for Uncertainty in Income Taxes, an interpretation of FASB Statement No. 109"* (FIN 48). FIN 48 clarifies the accounting for uncertainty in income taxes recognized in a company's financial statements and prescribes a recognition threshold and measurement attribute for financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return. This Interpretation also provides related guidance on derecognition, classification, interest and penalties, accounting in interim periods and disclosure. We adopted FIN 48 at the beginning of fiscal year 2007 with no material impact to our financial condition, results of operations, or cash flows.

In September 2006, the FASB issued SFAS No. 157, *Fair Value Measurements*, (SFAS 157). SFAS 157 defines fair value, establishes a framework for measuring fair value in generally accepted accounting principles, and expands disclosures about fair value measurements. The provisions of this standard apply to other accounting pronouncements that require or permit fair value measurements. We will adopt SFAS 157 on January 1, 2008. We anticipate that the adoption of SFAS 157 will not have a material impact on our consolidated financial statements.

In February 2007, the FASB issued SFAS No. 159, *"The Fair Value Option for Financial Assets and Financial Liabilities"* (SFAS 159). This Statement provides companies with an option to report selected financial assets and liabilities at fair value. Generally accepted accounting principles have required different measurement attributes for different assets and liabilities that can create artificial volatility in earnings. The Statement's objective is to reduce both complexity in accounting for financial instruments and the volatility in earnings caused by measuring related assets and liabilities differently. We will adopt SFAS 159 on January 1, 2008. We are currently evaluating the impact of this standard.

We have reviewed all other recently issued, but not yet adopted, accounting standards in order to determine their effects, if any, on our consolidated results of operation, financial position or cash flows. Based on that review, we believe that none of these pronouncements will have a significant effect on our current or future earnings or operations.

Results of Operations

The following table presents our results of operations for the three and nine months ended September 30, 2007 and 2006:

	Three Months Ended		Nine Months Ended	
	September 30, 2007	September 30, 2006	September 30, 2007	September 30, 2006
Revenue:				
Product sales	\$ 3,833,803	\$ 3,019,536	\$ 10,450,499	\$ 6,949,545
Royalties	1,121,053	923,114	2,958,559	1,884,731
Technology fees and licensing revenues	49,167	49,167	147,501	147,501
Development fees and related services	65,260	126,212	102,593	532,284
Total Revenue	<u>5,069,283</u>	<u>4,118,029</u>	<u>13,659,152</u>	<u>9,514,061</u>
Cost of revenue	<u>1,704,460</u>	<u>1,428,230</u>	<u>4,642,228</u>	<u>3,344,106</u>
Gross profit	<u>3,364,823</u>	<u>2,689,799</u>	<u>9,016,924</u>	<u>6,169,955</u>
Operating expenses:				
Research and development (totals include amortization of stock based compensation)	1,059,368	915,923	3,292,409	2,797,465
Sales and marketing (totals include amortization of stock based compensation)	282,671	428,740	1,177,231	1,064,351
General and administrative (totals include amortization of stock based compensation)	990,701	800,933	2,852,182	2,034,015
Total operating expenses	<u>2,332,740</u>	<u>2,145,596</u>	<u>7,321,822</u>	<u>5,895,831</u>
Income from operations	<u>1,032,083</u>	<u>544,203</u>	<u>1,695,102</u>	<u>274,124</u>
Other income (expense):				
Interest income	67,597	85,445	187,594	114,915
Other expense	(3,197)	(72,973)	(3,314)	(144,274)
Total other income (expense), net	<u>64,400</u>	<u>12,472</u>	<u>184,280</u>	<u>(29,359)</u>
Income tax provision	<u>(26,619)</u>	<u>-</u>	<u>(51,945)</u>	<u>(3,435)</u>
Net income	<u>\$ 1,069,864</u>	<u>\$ 556,675</u>	<u>\$ 1,827,437</u>	<u>\$ 241,330</u>

THREE AND NINE MONTHS ENDED SEPTEMBER 30, 2007 AND 2006

Revenue

	Three Months Ended September 30,			
	2007	2006	Change	% Change
Product sales	\$ 3,833,803	\$ 3,019,536	\$ 814,267	27%
Royalties	1,121,053	923,114	197,939	21%
Technology fees and licensing revenues	49,167	49,167	-	0%
Development fees and related services	65,260	126,212	(60,952)	-48%
Total Revenue	\$ 5,069,283	\$ 4,118,029	\$ 951,254	23%

	Nine Months Ended September 30,			
	2007	2006	Change	% Change
Product sales	\$ 10,450,499	\$ 6,949,545	\$ 3,500,954	50%
Royalties	2,958,559	1,884,731	1,073,828	57%
Technology fees and licensing revenues	147,501	147,501	-	0%
Development fees and related services	102,593	532,284	(429,691)	-81%
Total Revenue	\$ 13,659,152	\$ 9,514,061	\$ 4,145,091	44%

Product Sales

Product sales increased \$814,267 or 27% and \$3,500,954 or 50% for the three and nine months ended September 30, 2007, as compared to the three and nine months ended September 30, 2006.

The significant increase in product sales was primarily driven by increased sales to existing customers, of our leading safety Huber needle products, MiniLoc® Safety Infusion Set and SafeStep® Huber Needle Set, as well as new OEM sales of our PowerLoc® Safety Infusion Set to Bard Access Systems and Monoject™ Bone Marrow Biopsy Needles to Tyco Healthcare.

Furthermore, the nine months ended September 30, 2007 reflects a full period of SafeStep® product revenue related to the Med-Design merger as compared to five months of revenue for the nine month period ended September 30, 2006. Revenue from sales of SafeStep® increased \$1,881,145 for the nine months ended September 30, 2007 as compared to the nine months ended September 30, 2006.

Product Royalties

Product royalty income increased \$197,939 or 21% and \$1,073,828 or 57% for the three and nine months ended September 30, 2007, as compared to the three and nine months ended September 30, 2006. This increase is primarily attributable to increased royalty income from BD Medical related to the Vacutainer® Push Button Blood Collection Set and Integra™ Syringe product lines acquired in the Med-Design merger.

Technology Fees and Licensing Revenues

Technology fees and licensing revenues did not change over the comparable annual periods. We are currently amortizing two upfront payments ratably over the multi-year life of the related license agreements. One such prepayment of \$150,000 was received in 2003, and is being amortized over a five year period. A second prepayment of \$500,000 was received in 2005, and is being amortized over a three year period. No new license agreements have been entered into during 2007.

Development Fees and Related Services

Development fees and related services decreased \$60,952 or 48% and \$429,691 or 81% for the three and nine months ended September 30, 2007, as compared to the comparable periods in 2006. This decrease is related to the maturation of our funded development projects, which have moved into the production phase in 2007.

Cost of Revenue

	Three Months Ended September 30,			
	2007	2006	Change	% Change
Cost of revenue	\$ 1,704,460	\$ 1,428,230	\$ 276,230	19%

	Nine Months Ended September 30,			
	2007	2006	Change	% Change
Cost of revenue	\$ 4,642,228	\$ 3,344,106	\$ 1,298,122	39%

The cost of revenue increased \$276,230 or 19% in the three month period ended September 30, 2007 compared to the same period in 2006. The cost of revenue increased \$1,298,122 or 39% in the nine month period ended September 30, 2007, as compared to the same period in 2006. The increase in cost of revenue is attributable to the increase in product sales, partially offset by an 80% decrease in cost of revenue associated with development fees and related services.

Gross Profit

	Three Months Ended September 30,			
	2007	2006	Change	% Change
Gross Profit	\$ 3,364,823	\$ 2,689,799	\$ 675,024	25%
Profit Margin	66%	65%		

	Nine Months Ended September 30,			
	2007	2006	Change	% Change
Gross Profit	\$ 9,016,924	\$ 6,169,955	\$ 2,846,969	46%
Profit Margin	66%	65%		

Gross profit for the three months ended September 30, 2007 increased \$675,024 or 25%, compared to the three months ended September 30, 2006. Gross profit for the nine months ended September 30, 2007 increased \$2,846,969 or 46%, compared to the nine months ended September 30, 2006. The increase in gross profit is primarily attributable to the increase in our total revenue, particularly the increase in royalty revenue, which has minimal cost of revenue and cost savings realized by transitioning to multi-cavity molds for the component parts of our MiniLoc® Safety Infusion Set product line in July 2006. Additionally, development fees and related services, which carry a high cost of revenue, decreased significantly from the comparable periods.

Gross profit margin for the three and nine months ended September 30, 2007 was 66%, representing an increase of one percentage point compared to the 65% gross profit margin realized for the same periods ended September 30, 2006. The increase in gross profit margin is primarily attributable to cost savings realized by transitioning to multi-cavity molds for the component parts of our MiniLoc® Safety Infusion Set product line in July 2006, the increase in royalty revenue for which there is minimal cost of revenue, and the decrease in development fees for which there is high cost of revenue.

Operating Expenses

	Three Months Ended September 30,			
	2007	2006	Change	% Change
Research and development expense	\$ 1,059,368	\$ 915,923	\$ 143,445	16%
Sales and marketing expenses	282,671	428,740	(146,069)	-34%
General and administrative expenses	990,701	800,933	189,768	24%
Total Operating Expenses	\$ 2,332,740	\$ 2,145,596	\$ 187,144	9%

	Nine Months Ended September 30,			
	2007	2006	Change	% Change
Research and development expense	\$ 3,292,409	\$ 2,797,465	\$ 494,944	18%
Sales and marketing expenses	1,177,231	1,064,351	112,880	11%
General and administrative expenses	2,852,182	2,034,015	818,167	40%
Total Operating Expenses	\$ 7,321,822	\$ 5,895,831	\$ 1,425,991	24%

Research and Development

Research and development (“R&D”) expenses increased \$143,445 or 16% for the three months ended September 30, 2007 as compared to the three months ended September 30, 2006. The increase in R&D expenses is primarily due to an increase of \$72,685 for supply related expenses, \$24,108 in consultant related expenses incurred in the exploration of additional products, an increase of \$18,402 for depreciation of new R&D manufacturing equipment acquired during the last half of 2006 and first half of 2007, and an increase of \$16,686 in stock-based compensation.

Research and development expenses increased \$494,944 or 18% for the nine months ended September 30, 2007 as compared to the nine months ended September 30, 2006. The increase in R&D expenses is primarily due to an increase of \$117,235 for personnel related expenses for additional personnel, \$93,983 in consultant related expenses, \$70,520 in testing related expenses incurred in the exploration of additional products, \$92,998 in research and development supplies, an increase of \$83,152 for depreciation of new R&D manufacturing equipment acquired during the last half of 2006 and first half of 2007 and an increase of \$27,850 in stock-based compensation.

The remaining increase for both periods is due to a number of smaller increases in various expense categories related to the development and commercialization of new product applications based upon our SecureLoc™ technology, the exploration of additional products based upon our proprietary medical safety needle technologies, continued support of our manufactured product lines, and the development of product improvements to the SafeStep® Huber Needle Set product line acquired in the Med-Design transaction.

Sales and Marketing

Sales and marketing expenses decreased \$146,069 or 34% for the three months ended September 30, 2007, as compared to the three months ended September 30, 2006. The decrease is primarily due to a \$152,442 decrease in personnel related costs related to the reduction of sales personnel in 2007.

Sales and marketing expenses increased \$112,880 or 11% for the nine months ended September 30, 2007, as compared to the nine months ended September 30, 2006. This increase is primarily related to an increase of \$71,951 in commissions and distribution fees for our SafeStep® Huber Needle Set product line during the 2007 period. An increase of \$29,709 in trade show and travel related expenses related to our expanded line of product offerings and an increase in marketing supplies of \$29,297 related to the creation and distribution of new marketing materials for the expanded line of products.

General and Administrative

General and administrative expenses increased \$189,768 or 24% for the three months ended September 30, 2007, as compared to the three months ended September 30, 2006. The increase resulted primarily from increased personnel costs of \$169,057 related primarily to the addition of new finance and accounting employees, increased investor relation expenses of \$27,174 related to retaining the services of an investor relations firm, and an increase of \$54,376 in stock-based compensation offset by decreases in insurance and legal fees due to the termination of the Med-Design facility lease obligation in 2006.

General and administrative expenses increased \$818,167 or 40% for the nine months ended September 30, 2007, as compared to the nine months ended September 30, 2006. The increase resulted primarily from increased personnel costs of \$412,170 related primarily to the addition of new finance and accounting employees, increased stock-based compensation of \$115,050, increased consultant fees of \$87,971 related to costs incurred to comply with Sarbanes-Oxley and retaining the services of a mergers and acquisition firm, increased amortization of \$102,542 related to amortizing the license rights acquired in the Med-Design merger, increased investor relation expenses of \$83,529 related to retaining the services of an investor relations firm, and a number of smaller increases in various expense categories.

Other Income

	Three Months Ended September 30,			
	2007	2006	Change	% Change
Other income (expense):				
Interest income	\$ 67,597	\$ 85,445	\$ (17,848)	-21%
Other expense	(3,197)	(72,973)	69,776	-96%
Total other income, net	\$ 64,400	\$ 12,472	\$ 51,928	416%
Income tax provision	\$ (26,619)	\$ -	\$ 26,619	NM
NM = Not Meaningful				
	Nine Months Ended September 30,			
	2007	2006	Change	% Change
Other income (expense):				
Interest income	\$ 187,594	\$ 114,915	\$ 72,679	63%
Other expense	(3,314)	(144,274)	140,960	-98%
Total other income (expense), net	\$ 184,280	\$ (29,359)	\$ 213,639	728%
Income tax provision	\$ (51,945)	\$ (3,435)	\$ 48,510	NM
NM = Not Meaningful				

Other income consists primarily of interest income and interest expense. The \$51,928 increase for the three months ended September 30, 2007 is due to a decrease in interest expense related to a convertible note, which was paid in full on September 30, 2006, and a decrease in the expensing of deferred finance costs related to the issuance of warrants to Galen Partners in consideration for the convertible note, offset by a decrease in interest income due to lower investment returns on the invested funds during the three month period ended September 30, 2007, as compared to the same period in 2006.

The \$213,639 increase for the nine months ended September 30, 2007 resulted from an increase in interest earned on invested funds of \$4,175,000 as the funds were invested for the whole period in 2007 as compared to a portion of the period in 2006, a decrease in interest expense related to the convertible note and a decrease in the expensing of deferred finance costs related to the issuance of warrants to Galen Partners in consideration for the

convertible note. The Galen note, including all accrued interest, was paid in full on September 30, 2006. No further liabilities exist under the note agreement.

Income tax increased \$26,619 and \$48,510 for the three and nine months ended September 30, 2007, as compared to the comparable periods in 2006. The increase is due to increased franchise taxes related to the significant increase in Delaware franchise tax and an increase in estimated tax payments for state income taxes as we may be subject to 2007 income taxes in certain states. The Delaware tax is based on the number of outstanding shares or the total assets of the Company outstanding at year end, both of which increased significantly over the prior year due to the merger with Med-Design. We also recorded income tax expense of \$14,000 and \$30,000 for the three and nine months ended September 30, 2007, respectively, since we may be subject to alternative minimum tax in 2007. We recorded no income tax expense in 2006.

Net Income

Net income for the three and nine months ended September 30, 2007 increased \$513,189 or 92% and \$1,586,107 or 657%, respectively, compared to the three and nine months ended September 30, 2006. Basic and diluted net income per common share for the three and nine months ended September 30, 2007 was \$0.02 and \$0.03, respectively, compared to \$0.01 and \$0.00 net income per common share for the three and nine months ended September 30, 2006, respectively.

Liquidity and Capital Resources

Historically, our principal use of cash has been to fund ongoing operations. To date, we have financed our operations principally through private placements of equity securities, the sale of technology and patents, product sales and royalties, development fees, technology and license fees and proceeds from the sale of common stock.

We had \$4,097,117 in cash and cash equivalents as of September 30, 2007, representing an increase of \$1,815,437 from December 31, 2006. We also had \$4,175,000 of available-for-sale securities as of September 30, 2007 compared to \$4,275,375 at December 31, 2006. Total cash and cash equivalents and available-for-sale securities was \$8,272,117 at September 30, 2007 as compared to \$6,557,055 at December 31, 2006, representing an increase of \$1,715,062. Working capital as of September 30, 2007 was \$10,603,772, compared to \$7,472,966 as of December 31, 2006. This increase in cash and working capital in 2007 was primarily due to cash provided by operating activities and the maturity of marketable securities offset by purchases of long-term assets. Our working capital requirements for the foreseeable future will vary based upon a number of factors, including the costs to complete development work, the cost of bringing new safety medical needle technologies and other products to commercial viability, the timing of the market launches of new products and the level of sales of our current products.

We believe that existing cash and cash equivalents, available-for-sale securities, along with cash generated from the collection of accounts receivable, the sale of products, development fees and royalties, and available borrowings under our credit line will be sufficient to meet our cash requirements during the next twelve months.

Operating Activities

Net cash of \$2,187,585 was provided by operating activities during the nine months ended September 30, 2007, an increase of \$1,958,015 as compared to the \$229,570 provided during the same period in 2006. The \$2,187,585 provided by operating activities was primarily attributable to our positive net income of \$1,827,437, the positive cash impact of non-cash items such as depreciation and amortization, amortization of stock-based compensation and the decrease of accounts receivable offset by a significant decrease in accounts payable and other liabilities for which cash was used.

Investing Activities

Cash used in investing activities was \$373,748 for the nine months ended September 30, 2007, compared to \$2,386,556 provided by investing activities for the nine months ended September 30, 2006. During the nine months ended September 30, 2007, cash was used for the purchase of property and equipment and patent costs, offset by proceeds from the sale of marketable securities. During the nine months ended September 30, 2006, Med-Design was acquired, resulting in cash inflow of \$2,953,498, which was offset by cash purchases of property and equipment and intangibles of \$566,942.

Financing Activities

Cash provided by financing activities was \$1,600 for the nine months ended September 30, 2007 compared to cash used in financing activities of \$500,000 for the nine months ended September 30, 2006. During the nine months ended September 30, 2007, the cash provided by financing activities was from the exercise of a warrant by Galen Partners for 80,000 common shares at the exercise price of \$0.02. For the nine months ended September 30, 2006, cash proceeds of \$500,000 were realized from the draw against the Galen Partners promissory note, which was offset by the \$1,000,000 repayment of the note in full on September 30, 2006.

Credit Facility

On March 6, 2006, we obtained a \$1,500,000 revolving line of credit with Silicon Valley Bank under which borrowings will be collateralized by substantially all of our assets. Available borrowings are based primarily on outstanding accounts receivable. As of September 30, 2007, there was no outstanding balance on the revolving line of credit. The line has a maturity date of February 10, 2008, and carries an interest rate equal to 1.00 percentage point above the Prime Rate.

Contractual Obligations

Our significant non-cancelable operating lease obligations and purchase order commitments as of September 30, 2007 are as follows:

Obligation	Total	Payments Due by Year	
		2007 (1)	2008
Operating leases	\$ 296,436	\$ 64,072	\$ 232,364
Purchase order commitments	1,974,293	1,475,335	498,958
Total	<u>\$ 2,270,729</u>	<u>\$ 1,539,407</u>	<u>\$ 731,322</u>

(1) The amounts for 2007 only include payments to be made after September 30, 2007.

Due to the long lead-time of critical components for LiftLoc® and MiniLoc® Safety Infusion Sets, SecureLoc™ Safety Introducer Needle, and SafeStep® Huber Needle Set, we had issued \$1,974,293 in long-term purchase orders relating to these products as of September 30, 2007.

Off-Balance Sheet Arrangements

We do not have any off-balance sheet arrangements that have or are reasonably likely to have a current or future effect on our financial condition, results of operations or cash flows.

Forward-Looking Statements

With the exception of historical facts, the statements contained in Management's Discussion and Analysis of Financial Condition and Results of Operations, are "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995 that reflect our current expectations and beliefs regarding our future results of operations, performance and achievements. These statements are subject to risks and uncertainties and are based upon assumptions and beliefs that may not materialize. These forward-looking statements include,

but are not limited to, statements concerning our belief that recent accounting pronouncements will not have a significant effect on our current or future earnings, operations or financial statements, and that existing cash balances, together with future cash flows from operations and existing lines of credit will be sufficient to fund our cash requirements during the next twelve months.

In addition, when used in this report, the words or phrases “will likely result,” “expect,” “anticipate,” “will continue,” “intend,” “plan,” “believe” and similar expressions are intended to help identify forward-looking statements.

We wish to caution readers that our operating results are subject to various risks and uncertainties that could cause our actual results and outcomes to differ materially from those discussed or anticipated. Reference is made to the risks and uncertainties described below and in our Annual Report on Form 10-KSB and any amendments thereto (which contains a more detailed discussion of the risks and uncertainties related to our business). We also wish to advise readers not to place any undue reliance on the forward-looking statements contained in this report, which reflect our beliefs and expectations only as of the date of this report. We assume no obligation to update or revise these forward-looking statements to reflect new events or circumstances or any changes in our beliefs or expectations, except as required by law. Some of the risks and uncertainties that might cause actual results to differ from those anticipated include, but are not limited to, the following:

- we have a history of losses;
- our success is dependent on sales generated by our distribution and licensing partners;
- in 2006, over fifty percent of our revenues were generated under agreements with four of our corporate partners;
- we are dependent upon our licensing partners or contract manufacturers to manufacture our products;
- our medical devices must be cleared or approved by the FDA before they can be sold in the U.S.;
- there are negative pricing pressures on safety products;
- our business could be adversely affected by changes in safety medical product technology;
- our products may not be accepted by the market;
- our long-term success is dependent on the success of our research and development efforts;
- our success is dependent on our patents and proprietary rights;
- we may not have adequate resources to manage anticipated growth;
- we are dependent on management and technical personnel;
- because we are significantly smaller than the majority of our competitors, we may lack the resources needed to capture market share;
- we face potential product liability relating to failure of our safety products;
- uncertainties in the healthcare industry create uncertainties regarding medical safety products;
- anti-takeover provisions of our certificate of incorporation and bylaws may discourage non-negotiated takeover of our company;

- our common stock price may continue to be volatile;
- we have outstanding securities whose holders have been granted registration rights;
- we do not anticipate paying dividends in the foreseeable future;
- our common stock is subject to dilution;
- applicability of low priced stock risk disclosure requirements may adversely affect the prices at which our common stock trades; and
- we can provide no assurance of a liquid public market for our common stock.

Item 3. Controls and Procedures

Evaluation of Disclosure Controls and Procedures. Under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, we evaluated the effectiveness of the design and operation of our disclosure controls and procedures (as defined in Rule 13a-15(e) under the Securities Exchange Act of 1934 [the “Exchange Act”]). Based upon that evaluation, our Chief Executive Officer and Chief Financial Officer concluded that, as of the end of the period covered by this report, our disclosure controls and procedures were effective.

Changes in Internal Control Over Financial Reporting. During the most recent fiscal quarter covered by this report, there has been no change in our internal control over financial reporting (as defined in Rule 13a-15(f) under the Exchange Act) that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II — OTHER INFORMATION

Item 1. Legal Proceedings

Certain legal proceedings in which we are involved are discussed in Part I, Item 3 of our Annual Report on Form 10-KSB for the year ended December 31, 2006. The following discussion is limited to certain recent developments concerning our legal proceedings and should be read in conjunction with our Annual Report on Form 10-KSB. In addition, for more information regarding our legal proceedings, please see Note 4 included in Part 1, Item 1 – Financial Statements, which information is incorporated herein by reference.

In June 2007, Retractable Technologies, Inc. (“RTI”) filed a lawsuit against Becton, Dickinson and Company (“BD”) in the United States Court for the Eastern District of Texas, alleging that the BD Integra™ syringes infringe patents licensed exclusively to RTI. This patent claim was not covered by the release contained in the July 2004 settlement agreement between BD and RTI to settle the lawsuit previously filed by RTI. RTI also alleges in its lawsuit that BD engaged in false advertising with respect to certain of BD’s safety-engineered products in violation of the Lanham Act; acted to exclude RTI from various product markets and to maintain BD’s market share through, among other things, exclusionary contracts in violation of state and Federal antitrust laws; and engaged in unfair competition. The non-patent claims purport to relate to actions allegedly taken by BD following the date of the July 2004 settlement agreement referenced above. RTI seeks treble damages, attorney’s fees and injunctive relief. The Company is not a party to the patent infringement lawsuit brought by RTI against BD.

The Integra™ syringe is the subject of a license agreement dated March 12, 2000, and subsequently amended, between BD and the Med-Design Corporation (“BD Agreement”). Under the BD Agreement, in the event of (i) a final adjudication enjoining BD from making, using, or selling the Integra™ syringe or holding BD liable for damages based on the Integra™ syringe or (ii) settlement of the lawsuit requiring payment of damages by BD relative to the Integra™ syringe, BD has the right to deduct from future royalties sufficient to reimburse itself for one-half of its damages and legal expenses incurred and paid by BD in the lawsuit, but in no event shall BD’s royalty payments be reduced below a one percent (1%) royalty.

On September 6, 2007, Becton Dickinson and Company (“BD”) and MDC Investment Holdings, Inc. (“MDC”) filed a lawsuit against Retractable Technologies, Inc. (“RTI”) in the United States Court for the Eastern District of Texas, asserting that RTI’s VanishPoint® line of syringes infringe upon MDC’s United States Patent No. 6,179,812 (the “‘812 patent”), entitled “Retractable Needle Medical Devices,” and United States Patent No. 7,090,656 (the “‘656 patent”), entitled “Medical Devices with Retractable Needle.” BD and MDC seek damages, attorney’s fees and injunctive relief.

MDC is a wholly owned subsidiary of Med-Design Corporation. Med-Design Corporation is a wholly-owned subsidiary of Specialized Health Products International, Inc. Under a license agreement between BD and MDC, BD is the exclusive licensee with the right to sue for infringement of the ‘812 patent and the ‘656 patent and to join MDC as a party to such suit, in which event BD holds MDC free, clear and harmless from any and all costs and expenses of such litigation, including attorney’s fees.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds

None.

Item 3. Defaults Upon Senior Securities

None.

Item 4. Submission of Matters to a Vote of Security Holders

None.

Item 5. Other Information

None.

Item 6. Exhibits

- (a) Exhibit Index

EXHIBIT INDEX

<u>EXHIBIT NO.</u>	<u>DESCRIPTION OF EXHIBIT</u>
2.1	Agreement and Plan of Merger, dated as of November 21, 2005, among Specialized Health Products International, Inc. ("SHPI"), Mammoth Acquisition Sub, Inc., Mammoth Acquisition Sub, LLC., and The Med-Design Corporation (Incorporated by reference to Exhibit 99.1 to SHPI's Current Report on Form 8-K filed November 21, 2005).
2.2	First Amendment to the Agreement and Plan of Merger, dated as of November 21, 2005, among Specialized Health Products International, Inc., Mammoth Acquisition Sub, Inc., Mammoth Acquisition Sub, LLC., and The Med-Design Corporation (Incorporated by reference to Exhibit 2.2 to SHPI's Annual Report on Form 10-KSB filed March 10, 2006).
3(i).1	Restated Certificate of Incorporation of the Company (Incorporated by reference to Exhibit 3(i).1 of SHPI's Form 10-QSB, dated September 30, 2001).
3(i).2	Certificate of Designations, Preferences and Limitations of Series A Preferred Stock, dated November 6, 2001 (Incorporated by reference to Exhibit 3(i).2 of SHPI's Form 10-QSB, dated September 30, 2001).
3(i).3	Amendment to Restated Certificate of Incorporation (Incorporated by reference to Exhibit 3(i).3 of SHPI's Form 10-QSB, filed August 10, 2007).
3(ii).1	Third Amended and Restated Bylaws of SHPI (Incorporated by reference to Exhibit 99.3 to SHPI's Current Report on Form 8-K filed November 21, 2005).
10.1	Amendment to Employment Agreement with Mr. David A. Green (Incorporated by reference to Exhibit 10.1 of SHPI's Form 8-K, dated July 13, 2007).
31.1	Certification by Jeffrey M. Soinski under Section 302 of the Sarbanes-Oxley Act of 2002.
31.2	Certification by David A. Green under Section 302 of the Sarbanes-Oxley Act of 2002
32.1	Certification of Jeffrey M. Soinski pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2	Certification of David A. Green pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

SPECIALIZED HEALTH PRODUCTS
INTERNATIONAL, INC.

Date: November 7, 2007

By /s/ Jeffrey M. Soinski
Jeffrey M. Soinski
President, Chief Executive Officer, Director

Date: November 7, 2007

By /s/ David A. Green
David A. Green
Chief Financial Officer

I, Jeffrey M. Soinski, certify that:

1. I have reviewed this report on Form 10-QSB of Specialized Health Products International, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the small business issuer as of, and for, the periods presented in this report;
4. The small business issuer's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e) for the small business issuer and have:
 - a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the small business issuer, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - b. Paragraph omitted pursuant to SEC Release Nos. 33-8238 and 34-47986;
 - c. Evaluated the effectiveness of the small business issuer's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - d. Disclosed in this report any change in the small business issuer's internal control over financial reporting that occurred during the small business issuer's most recent fiscal quarter (the small business issuer's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the small business issuer's internal control over financial reporting; and
5. The small business issuer's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the small business issuer's auditors and the audit committee of small business issuer's board of directors (or persons performing the equivalent functions):
 - a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the small business issuer's ability to record, process, summarize and report financial information; and
 - b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the small business issuer's internal control over financial reporting.

Date: November 7, 2007

/s/ Jeffrey M. Soinski

Jeffrey M. Soinski

President, Chief Executive Officer, Director

I, David A. Green, , certify that:

1. I have reviewed this report on Form 10-QSB of Specialized Health Products International, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the small business issuer as of, and for, the periods presented in this report;
4. The small business issuer's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e) for the small business issuer and have:
 - a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the small business issuer, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - b. Paragraph omitted pursuant to SEC Release Nos. 33-8238 and 34-47986;
 - c. Evaluated the effectiveness of the small business issuer's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation, and
 - d. Disclosed in this report any change in the small business issuer's internal control over financial reporting that occurred during the small business issuer's most recent fiscal quarter (the small business issuer's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the small business issuer's internal control over financial reporting; and
5. The small business issuer's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the small business issuer's auditors and the audit committee of small business issuer's board of directors (or persons performing the equivalent functions):
 - a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the small business issuer's ability to record, process, summarize and report financial information; and
 - b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the small business issuer's internal control over financial reporting.

Date: November 7, 2007

/s/ David A. Green

David A. Green
Chief Financial Officer

**CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

In connection with the Quarterly Report of Specialized Health Products International, Inc. (the "Company") on Form 10-QSB for the period ending September 30, 2007 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Jeffrey M. Soinski, Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

(1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and result of operations of the Company.

/s/ Jeffrey M. Soinski
Chief Executive Officer
November 7, 2007

**CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

In connection with the Quarterly Report of Specialized Health Products International, Inc. (the "Company") on Form 10-QSB for the period ending September 30, 2007 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, David A. Green, Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

- (1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and result of operations of the Company.

/s/ David A. Green
Chief Financial Officer
November 7, 2007